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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,727	09/14/2005	Martin Krause	BB-124	1308
23557 7590 09/07/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER MEAH, MOHAMMAD Y	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 09/07/2007,	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,727

Applicant(s)

KRAUSE ET AL.

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

With preliminary amendment of this application, the applicant, on date 6/18/2007 elected with traverse Group I (claims 1-8) for further examination, amended claim 2 and withdrew claims 9-21.

Election/Restriction

During preliminary amendment of this application, the applicant, on date 6/18/2007 elected without traverse Group I (claims 1-8), drawn to methods of detection of and quantification of proteins using HPLC/MS after enzymatic cleavage from solid support. Groups II-V (claims 9-21) of election/restriction-office action of date 04/18/2007 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicant's election with traverse of group I (claims 1-8) in the reply filed on 6/18/2007 is acknowledged.

Applicants arguments of method steps in all these groups that distinguished only by enzymatic and chemical reaction should be examined together because enzymatic cleavage work through chemical reaction is not found to be persuasive as explained below:

As explained in the prior action these claims lack unity of invention as they are not linked by a special technical feature and therefore, according to USC 121 and 372, restriction between these groups is required. Furthermore, if search for enzymetic reaction and chemical reaction would be overlapping it would not be coextensive. Art that applies for enzymetic

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reaction may or may not be relevant to chemical reaction. Therefore the restriction is maintained and made FINAL.

Claim Rejections

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention.

These claims are directed to methods of identification and quantification of a genus of peptide using a genus of reagents comprising any metal chelate and any chemical compound bound to solid support and use of any enzyme to cleave the peptide from protein or solid support then using any HPLC/MS methodology. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of proteins or metal chelates, chemical coupling reagent and enzyme used in cleavage. Since extent of bounding and selectivity of peptide depend on the nature of chelate, linker group and cleavage depends on the nature of

enzyme and their respective the physical and chemical characteristics given this lack of description of representative protein, chelate, enzyme species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of purification of specific protein comprising using macrocyclic lanthanides chelate complex comprising DOTA macrocycle and biotin type linker group, not reasonably provide enablement for methods of identification and quantification of a genus of peptide using a genus of reagent comprising any metal chelate and any chemical compound bound to solid support and use of any enzyme to cleave the peptide from protein or solid support. then using any HPLC/MS methodology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claims 1-8 are so broad as to encompass methods of identification and quantification of a genus of peptide using a genus of reagent comprising any metal chelate and any chemical compound bound to solid support and use of any enzyme to cleave the peptide from protein or solid support. then using any HPLC/MS methodology. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins, as well as broad class of reagents used comprising any metal chelate and any chemical compound bound to solid support and any enzyme to cleave the peptide from protein or solid support. broadly encompassed by the methods of the claims. The specification fails to describe how any metal chelate selectively

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binds any protein and/ or peptide and any linker group binds said selected moiety to solid support then any enzyme cleaves the bound moiety from solid support. The specification fails to describe in any fashion the physical and/or chemical properties of the claimed class of protein, metal chelate linker group and cleaving reagent comprising any enzyme as discussed above. As the structure of the claimed substances are not defined in any way, one of ordinary skill in the art would not be able to make and use any such substances without undue experimentation to first find what substances in fact fall within the claimed class. Furthermore, the claimed class of compounds is likely to include many compounds, which one of ordinary skill in the art would be unable to make and use without undue experimentation, even if it was known or expected that the substance be within the scope of the claims.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including methods of identification and quantification of a genus of peptide using a genus of reagent comprising any metal chelate and any chemical compound bound to solid support and use of any enzyme to cleave the peptide from protein or solid support then using any HPLC/MS methodology. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substances having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

CLAIM Rejection - 35 U.S.C 102

35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Carr et al. (WO 0047548, from IDS).

Carr et al. et al. teaches method of purification of protein (such as antibody Fv) tagged with chemical functional groups comprising metal chelate reagent and label reagent (biotin) to bound to solid support and then enzymatic cleavage the said bound peptide and use HPLC/MS technique.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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